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17:40 - 17:55 Screening by the Back Door is Morally Unjustifiable -
Inappropriate Use of iFOBT.



Screening by the Back Door: Inappropriate Use of FOBT.

David Orr

Gastroenterologist

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NZSG Position Statement

The NZSG considers that testing the faeces of patients who have no gastrointestinal symptoms, of any age, for signs of occult blood loss is inappropriate outside of a fully funded Bowel Cancer Screening Programme. Even in symptomatic patients it is not a useful test, when appropriate specialist review and directed investigations are the correct approach. A positive FOB (iFOB or ≥ 2 of 3 Guaiac FOB tests) is statistically linked to a slightly increased possibility of lower GI pathology, however use of FOB tests in the well population outside BCSP not only leads to raised anxiety in patients with no symptoms, but, if referred onto the public health system for colonoscopy or CT Colonography, places a pressure on an already stressed system, where many symptomatic patients are still having to wait beyond acceptable periods.

April 2016

Bowel Cancer in NZ

- CRC is the second highest cause of cancer death
- 3000 are diagnosed annually, >1200 die from CRC
- Bowel screening reduces CRC deaths by 16- 22% at 10yrs
- Most patients with CRC initially consult primary care physicians
 - symptoms of rectal bleeding, altered bowel habit, weight loss, abdominal pain, IDA (or unexplained anaemia age >60) referred.

FOB Testing

- FOBT for colorectal cancer (CRC) screening is supported by RCTs, showing short and long term reduction in CRC incidence and mortality
- Guaiac (gFOB) test detects peroxidase activity
- Faecal immunochemical tests (FIT) directly measure human haemoglobin



FIT based screening

- FOBT is a screening tool for average risk, asymptomatic patients.
- FIT does not require adjustment in diet or anticoagulation or antiplatelet agents.
- FIT viewed as specific for lower GI bleeding as haemoglobin is degraded as it moves through the GI tract
- BCS is cost effective
- FOBT is **NOT** of additional benefit in symptomatic patients

FIT based screening

- Detection of CRC: FIT sensitivity 79%, specificity 94%; PPV 2-7%
- Detection of advanced adenoma: sensitivity 6-56%; PPV 33-54%

Study, year	FIT brand	FIT samples	Cut-off value, mg/g	Cohort size	AA, n	Reference standard	Sensitivity	Specificity
Sohn et al, ³⁶ 2005	OC-Hemodia ^a	1	20	3794	67	Colonoscopy	0.06	0.99
Morikawa et al, ³⁰ 2005	Magstream	1	67	21,805	648	Colonoscopy	0.22	0.95
Nakazato et al, ³⁴ 2006	OC-Hemodia ^a	2	16	3090	53	Colonoscopy	0.24	0.87
Levi et al, ²⁹ 2007	OC-Micro	3	15	80	15	Colonoscopy	0.53	0.89
Graser et al, ⁴⁰ 2009	FOB Gold ^a	1	2.4	265	24	Colonoscopy	0.29	0.85
Hundt et al, ⁴² 2009	Bionexia FOBplus ^a	1	2	1319	130	Colonoscopy	0.52	0.80
Hundt et al, ⁴² 2009	ImmoCARE-C ^a	1	30	1319	130	Colonoscopy	0.25	0.96
Hundt et al, ⁴² 2009	FOB advanced ^a	1	6	1319	130	Colonoscopy	0.27	0.91
Hundt et al, ⁴² 2009	QuickVue iFOB ^a	1	50	1319	130	Colonoscopy	0.56	0.68
Hundt et al, ⁴² 2009	PreventID CC ^a	1	2	1319	130	Colonoscopy	0.49	0.81
Haug et al, ⁴¹ 2010	Ridascreen ^a	1	14	1319	130	Colonoscopy	0.24	0.75
Park et al, ³³ 2010	OC-Micro	1	20	770	59	Colonoscopy	0.24	0.94
de Wijkerslooth et al, ²⁵ 2012	OC-Sensor	1	20	1256	119	Colonoscopy	0.29	0.97
Chiu et al, ²⁴ 2013	OC-Light	1	10	8822	632	Colonoscopy	0.28	0.93
Brenner and Tao, ²¹ 2013	OC-Sensor	1	6.1	2235	207	Colonoscopy	0.22	0.97
Brenner and Tao, ²¹ 2013	Ridascreen ^a	1	24.5	2235	207	Colonoscopy	0.21	0.97
Imperiale et al, ³⁷ 2014	OC-FIT CHEK	1	20	9899	760	Colonoscopy	0.24	0.94
Hernandez et al, ³⁸ 2014	OC-Sensor	1	20	779	92	Colonoscopy	0.28	0.96

A positive FIT

- Colonoscopy (+/- CTC) is recommended
- A positive FIT and a negative colonoscopy should not prompt an upper endoscopy
- Other causes for +ve FIT
 - diverticular disease
 - haemorrhoids
 - inflammatory bowel
 - angiodysplasia

Shortcomings of FOBT in Primary care.

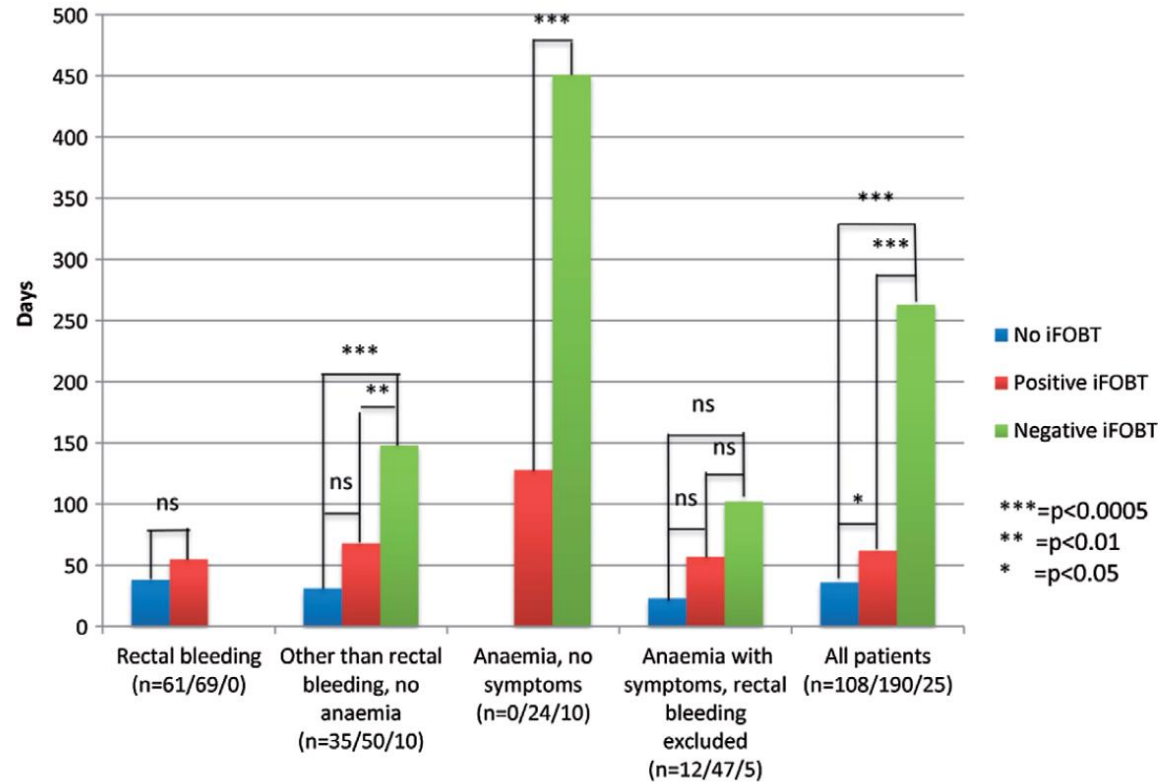
- Swedish cancer registry data (2005-09).
- **Symptomatic** patients
- Reported date of diagnosis of CRC or advanced adenoma
FIT within preceding 2 years of diagnosis recorded.

Results:

Table III. Symptoms and signs at the start of investigations in primary care and results of immunochemical faecal occult blood tests (iFOBTs) in 323 patients with CRC and adenomas with HGD.

	Rectal bleeding n = 116 + 14 ²	Other than rectal bleeding, no anaemia ¹ n = 83 + 12 ²	Anaemia, no symptoms n = 33 + 1 ²	Anaemia with symptoms, rectal bleeding excluded n = 62 + 2 ²	All patients n = 294 + 29 ²
No iFOBT performed	56 + 5 ²	29 + 6 ²	0 + 0 ²	11 + 1 ²	96 + 12 ²
IFOBT performed	60 + 9 ²	54 + 6 ²	33 + 1 ²	51 + 1 ²	198 + 17 ²
of which positive iFOBT	60 + 9 ²	46 + 4 ²	23 + 1 ²	46 + 1 ²	175 + 15 ²
of which negative iFOBT	0 + 0 ²	8 + 2 ²	10 + 0 ²	5 + 0 ²	23 + 2 ²

Shortcomings of FOBT in Primary care.



- FIT is often negative in patients with symptoms or anaemia (1 in 6 patients without rectal bleeding)
- A false negative result is associated with diagnostic delay

Outcomes of FOBT requested outside Bowel Cancer Screening Programme

FIT outside the UK National Bowel Cancer Screening Programme

- 715 gFOBT completed, (n=60)
8.4% +ve
- Mean age 60.4yr

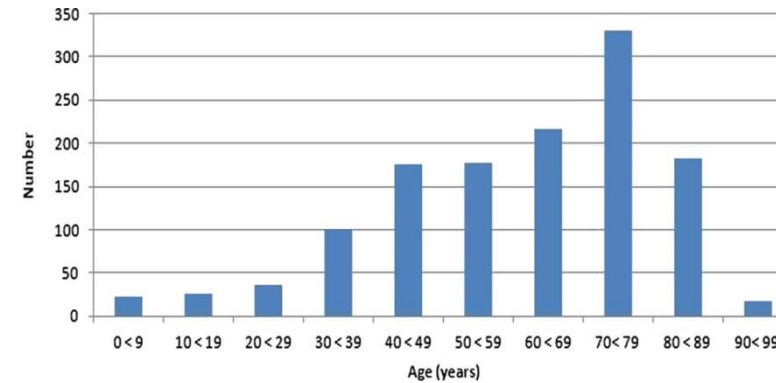


Table 2 Investigations performed in FOBT-positive patients

Investigation	n
OGD	27
Flexible sigmoidoscopy	12
Colonoscopy	8
Barium enema	6
CT scan	2
USS	1

FOBT, Faecal occult blood test; OGD, Gastroscopy; USS, ultrasound scan.

Table 4 Details of individual patients diagnosed with colonic cancer

Diagnosis	Age (years)	Indication for FOBT	Outcome
Adenocarcinoma Sigmoid colon	67	Change in bowel habit and rectal bleeding	Resection T4N0M0
Adenocarcinoma Ascending colon	70	Iron deficiency anaemia	Palliative care Liver and lung mets
Adenocarcinoma Ascending colon	71	Iron deficiency anaemia	Resection T4N1M0

FOBT, Faecal occult blood test; Liver and lung mets; Liver and lung metastases

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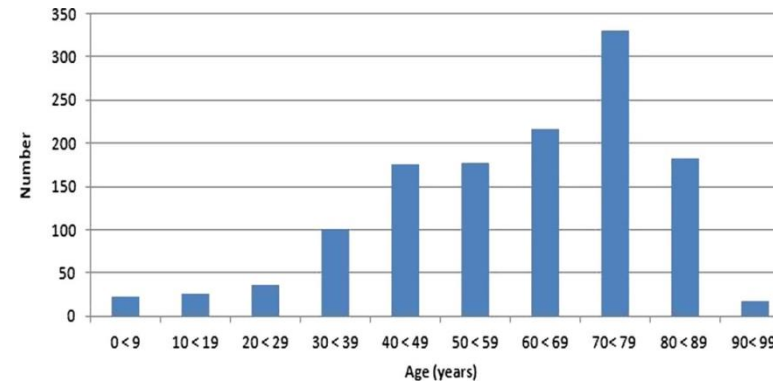


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FOBT, Faecal occult blood test; Liver and lung mets; Liver and lung metastases

22% with +ve FOB underwent total colonic imaging

Bowel Screening Pilot

Waitemata DHB 2011 to Dec 2017

- Participation: 56.8% (% invited)- target >60%
- FIT Positivity rate: 7.5% tests +ve
- +ve FIT undergoing colonoscopy or CTC 88.1% - target >90%
 - Major colonoscopy complication rate 3.5 per 1,000
- CRC detection: 2.8 per 1000 screened with FIT (target 1.8-9.5)
 - PPV 4.3% (2/3 diagnosed at stage 1 or 2)
 - Advanced adenoma: 15.5 per 1000
 - PPV 24.0%
 - Adenoma detection: 36.2 per 1000
 - PPV 56.1%

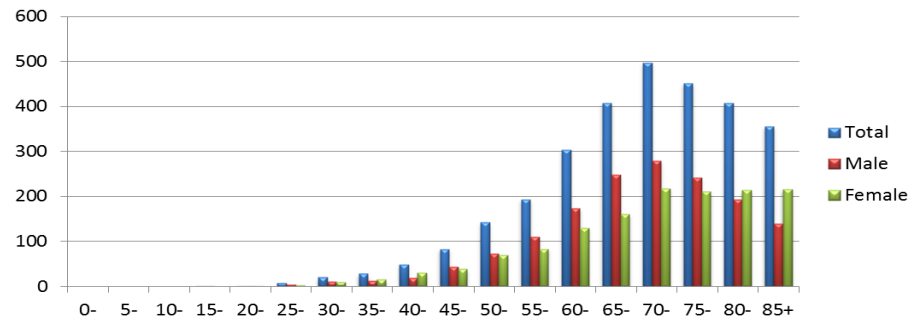
NZ Bowel Screening Roll-out

2017- 18	2018- 19	2019- 20
Waitemata DHB	Northland DHB	Bay of Plenty DHB
Hutt Valley DHB	Auckland DHB	Tairāwhiti DHB
Wairarapa DHB	Waikato DHB	Lakes DHB
Counties DHB	Hawkes Bay DHB	Taranaki DHB
Southern DHB	Whanganui DHB	West Coast DHB
	MidCentral DHB	
	Capital & Coast DHB	
	Nelson Marlborough DHB	
	Canterbury DHB	
	Sth Canterbury DHB	

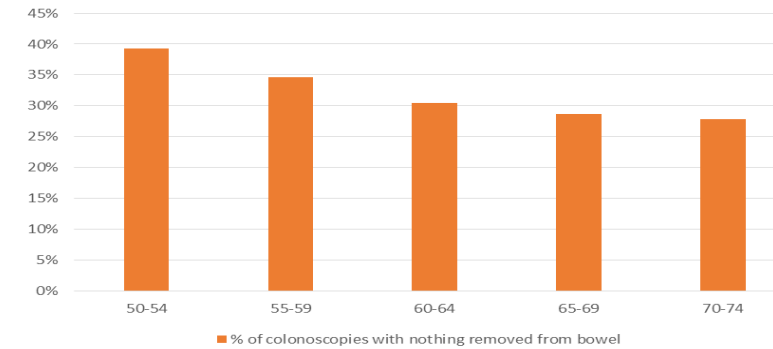
- Estimated colonoscopy requirements for screening:
~6.4% FIT +ve, 60% participation requires 18,000 colonoscopies nationally, increasing to 28,000/yr by 2031

NZ Bowel Screening Roll-out

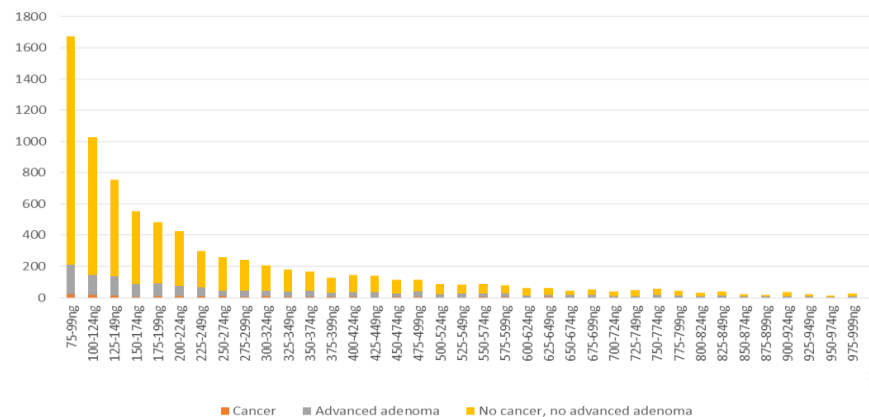
Average number of annual colon and rectal cancer registrations by age and sex
2010-2012 average



% of colonoscopies that required no polyps to be removed by age band



Number of colonoscopies performed by FIT result range and outcome



Screening Age range and Positivity threshold

- Age 60-74
- FIT threshold: 200ng Hb/ml

Conclusions

- FOBT is a **screening** tool for **asymptomatic** average risk population.
- FOBT has no place in the assessment of symptomatic &/or anaemic patients.

A false negative test delays diagnosis of CRC

Undertaking FOBT outside a screening programme will increase pressure on stretched, under-resourced endoscopy units that may result in delays of endoscopy in symptomatic patients.

Outside a BCS programme, patients are more likely to not complete the FOB test or undergo subsequent colonoscopy if the test is positive

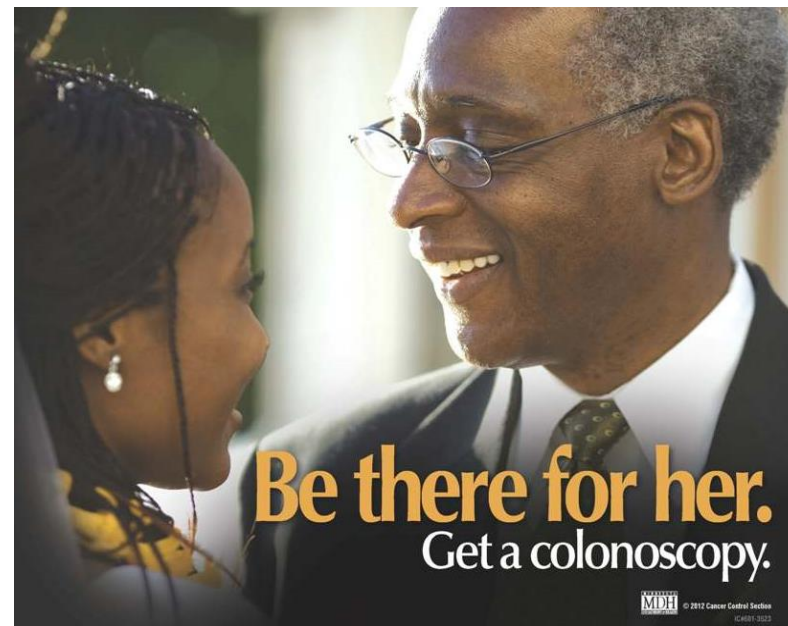
- BCSPs are due to be rolled out in NZ over the next 2-3 years



Embarrassment can't kill you.
Colon cancer can.

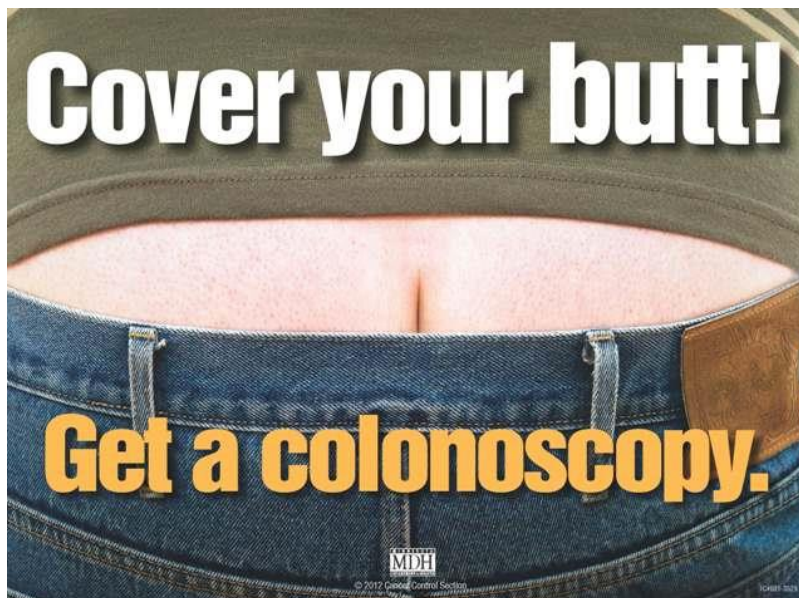
Get tested.

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Be there for her.
Get a colonoscopy.

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Cover your butt!

Get a colonoscopy.

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There's a better way.
Get a colonoscopy.

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